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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,663	12/06/2000	Michael J. Hageman	01-677	8091

7590 03/21/2003

PHARMACIA CORPORATION
PATENT DEPARTMENT - 04B
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ST LOUIS, MO 63167

EXAMINER

SHAMEEM, GOLAM M

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,663

Applicant(s)

HAGEMAN ET AL.

Examiner

Golam M M Shameem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-14 and 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1-35 are pending in the application. Claims 2-14 and 16-35 are withdrawn from consideration by the Examiner under 37 C.F.R. 1.142 (b) as directed to non-elected subject matter.

Response to Election/Restriction

Applicant's election without traverse of Group I, which includes claims 1 and 15 in paper No.9 filed on March 25, 2002, is acknowledged. The requirement for restriction in Paper No. 6 is deemed proper and is therefore made FINAL.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Response to Arguments

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tally et al (US Pat No 5,466,823) of record and the rejection has been maintained for the reasons given in the last office action (paper No. 11). Applicant's arguments have been fully considered but are not deemed persuasive due to the following reasons. Applicant alleges, "no suggestion or motivation to modify Talley's crystalline celecoxib to make amorphous celecoxib is found either in Talley itself or in the knowledge generally available to one of ordinary skill in the art at the time the invention was made" (Response, page 2). Applicant further argues, "it was not even predictable that an amorphous form of celecoxib could exist or be made." This assessment is speculation on applicant's behalf because one of ordinary skill in the art deemed to be aware of all the pertinent art in the field. Stavchansky et al (1990) teach that amorphous solids will, in general, be better absorbed than will crystalline ones (lines 11-12, page 463) and amorphous

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state generally reduce the particle size of the drug and result in a faster rate of dissolution than occurs with a crystalline form (lines 5-7, page 465). Therefore, one skilled in the art would have been motivated to prepare amorphous forms of a known compound with a reasonable expectation that such changing the forms/state of a compound would results compounds of similar activity. Mere change of form in and of itself does not disclose novelty. Ex parte Conn and Norman, 119 USPQ 388, 1956. This is enough motivation unless un-obviousness and unexpected results can be shown and hence, this rejection must be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703) 308-4532. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

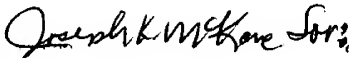
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

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data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

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Art Unit 1626, Group 1620
Technology Center 1


Celia C Chang, Ph.D.
Primary Patent Examiner
Art Unit 1625, Group 1620
Technology Center 1

March 19, 2003